AcuCort reports positive outcome of the expert group work

AcuCort AB (Spotlight Stock Market: ACUC) today reports a positive view, concluding that the outcome of the second bioequivalence study for the US is not considered an obstacle for a market application for US registration of the company's drug candidate ISICORT®.

As previously announced in a press release (November 8, 2019) AcuCort has appointed an expert group with the task to evaluate the results of the second study for the US market, with non-fasting patients, where two of the three criteria for bioequivalence were met.

The group has analyzed possible causes for the deviation and has been able to select the most likely cause. This has to do with the fact that two different oral pharmaceutical formulations are compared in the clinic. This results in some pharmacokinetic differences.

The expert group has furthermore presented options for courses of action to enable the process of registration and commercialization of ISICORT® on the US market, and AcuCort sees a suitable option to pursue. These conclusions have furthermore been confirmed by two independent regulatory expert bodies in the US and in Germany.

The group has also identified that the study design could have included more data points. The management of AcuCort has therefore decided on a pharmacokinetic modeling and simulation study to be performed by experts, in order to ensure the best possible knowledge of the product's performance under non-fasting conditions for the continued registration work.

"As this is a US 505(b)(2) application and not a generics application, certain deviations should be acceptable. Since we have received confirmation on this from further regulatory expert bodies, we at AcuCort have concluded that there are good possibilities to work for a US registration. I am very happy to be able to communicate this. We look forward with confidence to the continued work with registration in Sweden as well as in the US," says Ann Gidner, interim CEO of AcuCort.

For further information, please contact
Ann Gidner, interim CEO of AcuCort AB

Phone: +46 72 315 1414

E-mail: ann.gidner@acucort.se

About drug registration and pharmacokinetics

In the US, the corresponding relevant application is called FDA 505(b)(2). The same principles as in the EU apply, i.e. ISICORT® shall be evaluated in terms of bioequivalence and safety against a Reference Listed Drug (RLD).

Bioequivalence is a term in pharmacokinetics (the study of drug circulation and absorption in the body) used to describe equal medical effect of two drugs.

About AcuCort
AcuCort develops and commercializes ISICORT®, a new fast-dissolving oral film to put on the tongue, based on a well-known cortisone substance – dexamethasone. ISICORT® is a smart product in a new, innovative, patented and user-friendly dosage form primarily for the treatment of severe and acute allergic reactions, croup in children and chemotherapy-induced nausea and vomiting (CINV). The bioequivalence study that forms the basis of the application for marketing approval in Europe was carried out with positive results and a national hybrid application has been submitted to the Swedish Medical Products Agency. Alltogether, this strengthens the company's assessment that the time tocommercialization of ISICORT® may be relatively short. AcuCort (ticker: ACUC) is listed on the Spotlight Stock Market in Sweden. Learn more at www.acucort.com.